UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
SOUTHEASTERN DIVISION

MICHELLE LAXTON,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	
	)	**No. 1:16-cv-193 SNLJ**
TEVA PHARMACEUTICALS USA, INC.,	)	
d/b/a GATE PHARMACEUTICALS, et al.	)	
	)	
Defendants.	)	

MEMORANDUM & ORDER

Plaintiff initially filed this lawsuit against defendant Teva Pharmaceuticals USA, Inc., d/b/a Gate Pharmaceuticals in circuit court in Cape Girardeau County, Missouri. Defendant removed the matter to this Court pursuant to this Court's diversity jurisdiction, 28 U.S.C. § 1332(a)(1). The lawsuit alleges that defendant Teva developed, manufactured, and marketed the prescription weight-loss drug Phentermine in its generic form and the brand name drug Adipex P. Plaintiff claims that defendant Teva failed to warn that Phentermine and Adipex P cause blood clots and that she was injured when she took these products. She claimed Teva was liable for Failure to Warn and Design Defect (Count I) and in Strict Liability (Count II). After removal to this Court, plaintiff amended her complaint to add defendants the United States Food and Drug Administration ("FDA"), Commissioner of Food and Drugs Robert Califf in his official capacity, and Secretary of Health and Human Services Sylvia Matthews Burwell in her official capacity (the "federal defendants"). Plaintiff added Count III against the federal

defendants for a declaratory judgment that FDA policies and procedures that prevent generic drug manufacturers from warning consumers about the risks of their products are arbitrary, capricious, unreasonable, and void as against public policy.

Defendant Teva moved to dismiss plaintiff's complaint. The Court granted that motion because the Supreme Court of the United States has held that the makers of generic drugs may not be sued under state law for failing to warn customers about the risks associated with their products. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011); *see* #15 at ¶¶ 32, 36. Counts I and II were dismissed on November 28, 2016.

The federal defendants have now moved to dismiss Count III. The matter has been fully briefed and is now ready for disposition.

I. Legal Standard

The purpose of a Rule 12(b)(6) motion to dismiss for failure to state a claim is to test the legal sufficiency of a complaint so as to eliminate those actions "which are fatally flawed in their legal premises and deigned to fail, thereby sparing litigants the burden of unnecessary pretrial and trial activity." *Young v. City of St. Charles*, 244 F.3d 623, 627 (8th Cir. 2001) (citing *Neitzke v. Williams*, 490 U.S. 319, 326-27 (1989)). "To survive a motion to dismiss, a claim must be facially plausible, meaning that the 'factual content. . . allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Cole v. Homier Dist. Co., Inc.*, 599 F.3d 856, 861 (8th Cir. 2010) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)).

II. Discussion

The Supreme Court held in *Mensing* that because generic drug manufacturers are required by federal law to use the same warning label as its name-brand counterpart, federal law preempted state laws that might otherwise require the manufacturer to label its drug to warn of product dangers. 564 U.S. at 618. Plaintiff claims the "policies and procedures the FDA employs that prevent generic drug manufacturers from warning consumers/patients about the risks of their products are arbitrary, capricious, unreasonable and void as against public policy." (#15 at ¶ 35.) Plaintiff states that the Supreme Court relied on those "void policies and procedures" when it made its ruling in *Mensing.*

Plaintiff thus asks the Court to declare that the "policies and procedures the FDA employs that prevent generic drug manufacturers from warning consumers/patients about the risks of their products are arbitrary, capricious, unreasonable and void as against public policy" and to allow plaintiff to proceed with prosecution of her claims against Teva.

The federal defendants make several arguments in favor of dismissing plaintiff's claims against them.

Defendant's arguments for dismissal for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6) include that she failed to exhaust administrative remedies, that she failed to challenge a specific policy or procedure, and that she failed to identify an applicable waiver of sovereign immunity.

Exhaustion of administrative remedies is generally required before proceeding to federal court to see review of the actions or policies of a federal administrative agency. *Darr v. Carter*, 640 F.2d 163, 165 (8th Cir. 1981). The Administrative Procedure Act

("APA") authorizes judicial review only with respect to "final agency action," 5 U.S.C. § 704, and an agency action is final for purposes of the APA only after a plaintiff "has exhausted all administrative remedies expressly prescribed by statute or agency rule." *Darby v. Cisneros*, 509 U.S. 137, 146 (1993). The Court notes that exhaustion requirements are not without exception, and the "general test" applied by the Court "permits resort to the courts without exhaustion when a litigant's need for immediate judicial review outweighs the efficiency and administrative autonomy that the exhaustion doctrine is designed to further." *Darr*, 640 F.2d at 165.

Defendants point out that plaintiff has made no attempt to avail herself, much less exhaust, the administrative remedy available to her, which is to file a citizen petition with the FDA pursuant to 21 C.F.R. §§ 10.25 and 10.30. FDA regulations require that "before any legal action is filed in a court," a party must first use the citizen petition process to "request that the Commissioner take or refrain from taking any form of administrative action." 21 C.F.R. § 10.45(b). That same regulation requires the Commissioner to request dismissal of the court action "for an initial administrative determination on the grounds of a failure to exhaust administrative remedies" in the event such an a court action is filed before a citizen petition. *Id.*

Defendants states that plaintiff should have requested the FDA to consider the issues in this matter and apply the agency's interpretation of the labeling regulations to these facts, including (1) whether Teva could have unilaterally changed the phentermine and Adipex-P labeling through a changes-being-effected or "CBE" submission, and (2) whether a labeling regime other than the one at issue in *Mensing* might apply to Adipex-P

and the generic phentermine at issue here.[1] Any interested person --- *e.g.*, Teva --- could thereafter submit comments and present alternative views. 21 C.F.R. § 10.30(d). The FDA's response to such a petition would then constitute final agency action subject to judicial review. *Id.* § 10.45(d).

Because plaintiff merely added Count III against the federal defendants to her existing products liability lawsuit rather than engaging in the citizen petition procedure outlined above, the FDA did not have an opportunity to consider and potentially resolve plaintiff's concerns. Plaintiff responds that exhaustion would have been futile because "there is a certainty of an adverse decision" and because "determination of the constitutionality of a statute" is "outside the agency's power to grant effective relief." (#40 at 5.) However, "[u]nsupported and speculative claims of futility do not excuse a claimant's failure to exhaust his or her administrative remedies." *Midgett v. Wash. Group Int'l Long Term Disability Plan*, 561 F.3d 887, 898 (8th Cir.2009) (quotation and alterations omitted). Here, plaintiff asserts that an "adverse decision" is "certain" without any support or discussion. Although plaintiff suggests that defendant is unable to grant it effective relief, the FDA points out that --- even if the constitutionality of the FDA's regulations were at issue here --- the FDA can and should consider questions of the constitutionality of its own regulations. *See Munsell v. U.S. Dept' of Agric.*, 509 F.3d 572, 591 (D.C. Cir. 2007) ("There is a strong rationale for requiring constitutional claims against USDA to be raised first in the administrative process."); *Volvo GM Heavy Truck Corp. v. U.S. Dept. of Labor*, 118 F.3d 205, 215 (4th Cir. 1997) ("exhaustion can be useful even where a constitutional issue is presented"). Plaintiff has never raised any

[1] Defendants point out that *Mensing* did not consider drugs like those here that were approved pursuant to an abbreviated drug application before passage of the 1984 Hatch-Waxman Amendments, which govern the current approval process.

objection to the FDA's drug labeling regulations, policies, and procedures, let alone raised a constitutional objection, and she may not do so through her opposition memorandum. Plaintiff must first do so with the agency to exhaust her administrative remedies so that there is a record for judicial review. Dismissal is appropriate in light of plaintiff's failure to avail herself of the administrative process. *Ass'n of Am. Physicians & Surgeons, Inc. v. Food & Drug Admin*., 539 F. Supp. 2d 4, 24 (D.D.C. 2008), aff'd sub nom. *Ass'n of Am. Physicians v. FDA*, 358 Fed. Appx. 179 (D.C. Cir. 2009) ("the Court should not attempt to resolve these arguments before the FDA has the opportunity to apply its expertise and a record is developed. Because the plaintiffs have failed to exhaust the administrative process mandated by regulation, dismissal of plaintiffs' amended complaint is warranted").

Plaintiff's complaint against the federal defendants must be dismissed for the additional reason that plaintiff has failed to challenge a specific agency policy or procedure. Although the Federal Rules of Civil Procedure require that plaintiff's complaint contain "a short and plain statement showing that the pleader is entitled to relief," Fed. R. Civ. P. 8(a)(2), plaintiff's generalized challenge to FDA policies and procedures that "prevent generic drug manufacturers from warning consumers/patients about the risks of their products" does not provide notice to the agency regarding what exactly she claims the FDA did that is "arbitrary, capricious, unreasonable and void as against public policy." (#15 at ¶ 35.) Again, this defect likely would have been cured had plaintiff first brought her grievance to the FDA through a citizen petition, as described above.

Although defendants rely upon several other theories to support their motion to dismiss, the Court need not reach those arguments. Defendants' motion will be granted.

Accordingly,

IT IS HEREBY ORDERED that defendants' motion to dismiss (#38) is GRANTED.

IT IS FURTHER ORDERED that in light of this Court's November 28, 2016 Memorandum and Order, this matter will be dismissed in its entirety.

Dated this 8th day of March, 2017.

STEPHEN N. LIMBAUGH, JR.
UNITED STATES DISTRICT JUDGE